

## PATENT COOPERATION TREATY 10/52375

From the:

Level 15

INTERN ONAL PRELIMINARY EXAMINING AUTHORITY

FRIDAY 28 HOY 2004

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

EDH

Date of mailing day/month/year

7 5 NOV 2004

Applicant's or agent's file reference

12301210/EJH/MLO

Davies Collison Cave

1 Nicholson Street MELBOURNE VIC 3000

IMPORTANT NOTIFICATION

International Application No. PCT/AU2003/001011

International Filing Date 8 August 2003

Priority Date

8 August 2002

Applicant

THE CORPORATION OF THE TRUSTEES OF THE ORDER OF THE SISTERS OF MERCY IN QUEENSLAND et al

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all
  the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

Name and mailing address of the IPEA/AU

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12301210/EJH/MLO	FOR FURTHER See Notification of Transmittal of I ACTION Examination Report (Form PCT/IP		Transmittal of International Preliminary (Form PCT/IPEA/416).					
International Application No.	International Filing Date (day/month/year)		Priority Date (day/month/year)					
PCT/AU2003/001011	8 August 2003	August 2003 8 August 2002						
International Patent Classification (IPC) or national classification and IPC								
Int. CI. ' A61K 39/395, A61P 37/06								
Applicant  THE CORPORATION OF THE TRUSTEES OF THE ORDER OF THE SISTERS OF MERCY IN QUEENSLAND et al								
1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.								
2. This REPORT consists of a total of 3	sheets, including this c	over sheet.	٠.					
This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).								
These annexes consist of a total	of sheet(s).	·.						
3. This report contains indications relating	g to the following items:							
I X Basis of the report								
II Priority	I Priority							
III Non-establishment of o	pinion with regard to nov	elty, inventive step a	and industrial applicability					
IV Lack of unity of inventi	Lack of unity of invention							
V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement								
VI Certain documents cited	Certain documents cited							
VII Certain defects in the in	Certain defects in the international application							
VIII Certain observations on	Certain observations on the international application							
Date of submission of the demand	· · · · · · · · · · · · · · · · · · ·	Date of completion	of the general					
27 February 2004		23 November 200	• •					
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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/AU2003/001011

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement		
Novelty (N)	Claims 5, 9, 10, 14 to 19, 22 and 24 to 32	YES
	Claims 1 to 4, 6 to 8, 11 to 13, 20, 21 and 23	NO
Inventive step (IS)	Claims 5, 9, 10, 14 to 19, 22 and 24 to 32	YES
	Claims 1 to 4, 6 to 8, 11 to 13, 20, 21 and 23	NO
Industrial applicability (IA)	Claims 1 to 32	YES
	Claims nil	NO

- 2. Citations and explanations (Rule 70.7)
- D1 Prickett, TCR et al, Immunology 1990 (69) pp250 256.
- D2 Hauss, P et al, European Journal of Immunology, 1995 (25) pp2285-2294.
- D3 WO 93/05814 A1 (The General Hospital Corporation) 1 April 1993.
- D4 WO 01/40308 A1 (The Corporation of the Trustees of the Order of the Sisters of Mercy in Queensland) 7 June 2001.
- D5 WO 01/87337 A1 (GPC Biotech AG, Morphosys AG) 22 November 2001
- D6 WO 02/051430 A2 (Synovis Limited) 4 July 2002.
- D7 WO 02/058721 A1 (Baylor College of Medicine) I August 2002.

The invention seems to lie in the specific use of a monoclonal antibody against antigen presenting cells, (APCs) particularly dendritic cells, carrying a CMRF antigen. This feature does not appear in the definitions of claims 1 to 3, 6 to 8 and 11 to 13. Consequently they are not novel and have no inventive step in comparison to D1 and D2 which disclose modulation of the immune activities of dendritic cells.

D3 discloses modulation of antigen presenting cell activity by a protein acting through the interaction of APCs with other cells. The soluble protein may be a monoclonal antibody. Claims 1, 2, 6 to 8, 11, 13, 20, 21 and 23 are not novel and have no inventive step in comparison.

D4 discloses modulation of stimulated dendritic cell activity. The agent may be a monoclonal antibody to CMRF-58. Claims 1, 2, 6 to 8, 11, 13, 20, 21 and 23 are not novel and have no inventive step in comparison.

D5 discloses killing cells which express HLA-DR, an immuno-active substance with an antibody based peptide. Claims 1, 2, 6 to 8, 11 to 14, 20 and 23 are not novel and have no inventive step in comparison. I

D6 discloses stimulation of APCs including dendritic cells by blocking Toll-related receptor signalling and inhibition by enhancement of the same signalling. Claims 1 to 3, 6 to 8, 11 to 13 and 20 are not novel and have no inventive step in comparison.

D7 discloses modulation of myeloid cell activation and immune response by changing DAP12/TREM-1 activity. Claims 1 to 4, 6 to 8, 11 to 13 and 20 are not novel and have no inventive step in comparison.



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